BIOSERVICE
SCIENTIFIC LABORATORIES GmbH

Classification of Plastics - Plastic Class VI – 121 °C

(Systemic Injection Test-Intraperitoneal Administration)

(Systemic Injection Test-Intravenous Administration)

(Intracutaneous Test)

(Implantation Test)

with

Teadit 24SH

Report

BSL BIOSERVICE Project No.: 041502

Sponsor

Teadit International Produktions GmbH
Rosenheimer Str. 10
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Austria

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GLP zertifiziert

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten
vertreten im
Deutscher Akkreditierungs Rat

Copy of the GLP-certificate

BAYERISCHES LANDESAMT
FÜR ARBEITSSCHUTZ,
ARBEITSMEDIZIN UND SICHERHEITSTECHNIK
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LfAS

GLP-Bescheinigung/Statement of GLP Compliance
(gemäß/according to § 19b Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 88/320/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 88/320/EEC at:

☒ Prüfeinrichtung/Test facility ☐ Prüfstandort/Test site

BSL Bioservice Scientific Laboratories GmbH
Behringstrasse 6
82152 Planegg
(Unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien/Areas of Expertise
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

2 Prüfungen auf toxikologische Eigenschaften
3 Prüfungen auf mutagene Eigenschaften (in vitro/in vivo)
9 Sonstige Prüfungen:
a) Mikrobiologische Sicherheitsprüfungen
b) Wirksamkeitsprüfungen an Zellkulturen

Datum der Inspektion/Date of Inspection
(Tag.Monat.Jahr/day.month.year)
11./12.02.2004

Die/Der genannte Prüfeinrichtung/Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

The above mentioned test facility/test site is included in the national GLP Compliance Programme and is inspected on a regular basis.

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/ diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

Based on the inspection report it can be confirmed, that this test facility/test site is able to conduct the aforementioned studies in compliance with the Principles of GLP.

München, 21.07.2004

I.V.
Ritter
Leitender Gewerbedirektor

L.S.

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Preface

General

Sponsor:	Teadit International Produktions GmbH Rosenheimer Str. 10 A-6330 Kufstein Austria
Study Monitor:	Mr Thomas Steffl
Test Facility:	BSL BIOSERVICE Scientific Laboratories GmbH Behringstrasse 6 82152 Planegg Germany
BSL BIOSERVICE- Project No.:	041502
Test Item:	Teadit 24SH
Title:	Classification of Plastics - Plastic Class VI - 121 °C with Teadit 24SH

Project Staff

Study Director:	Dr. Achim Albrecht
Deputy Study Director:	Dr. Ingrid Haist
Management:	Dr. Wolfram Riedel Dr. Angela Lutterbach
Quality Assurance Unit:	Dipl. Biol. Uwe Hamann Dr. Margarete Hoechst Dr. Helga Köhn

Schedule

Arrival of Test Item:	July 07, 2004
Date of Project Protocol:	July 08, 2004
Start of Study :	July 18, 2004
End of Study:	July 27, 2004
Date of Report:	July 29, 2004

Project Staff Signatures

Study Director: Dr. Achim Albrecht

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Date: 29 July 2004

Management:

.....

Date: 29- July - 2004

Quality Assurance

This study was conducted to comply with:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended on May 08, 2001. Published May 14, 2001 in Bundesgesetzblatt 2001 part I no. 21, pp. 844 – 854.

OECD Principles of Good Laboratory Practice (as revised in 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring - Number 1.
Environment Directorate, Organisation for Economic Co-operation and Development, Paris 1998.

This study was assessed for compliance with the project protocol, the study plan and the Standard Operating Procedures of BSL BIOSERVICE. The study and/or the test facility were periodically inspected by the Quality Assurance Unit and the dates and phases of the inspections and audits are included in this report. These inspections and audits were carried out by the Quality Assurance Unit, personnel independent of the staff involved in the study. The final report of the study was audited. A Quality Assurance Statement, signed by the Quality Assurance, is included in this report.

The test method is part of the BSL BIOSERVICE accreditation scope according to guideline 90/385/EWG, 93/42/EWG and DIN EN ISO/IEC 17025 for testing of medical devices.

Guidelines

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

USP "Biological Reactivity Tests, in vivo - Classification of plastics"

Archiving

The following records will be stored in the scientific archives of BSL BIOSERVICE Scientific Laboratories GmbH according to the GLP regulations:

A copy of the final report, the project protocol, the study plan and a documentation of all raw data generated during the conduct of the study (documentation forms as well as any other notes of raw data, printouts of instruments and computers) and the correspondence with the sponsor concerning the project.

If test item is left over a sample will be stored according to the period fixed by the GLP-Regulations. Samples that are unstable may be disposed of before that time. Unless otherwise agreed upon, remaining test item will be discarded three months after release of the report.

Statement of Compliance

BSL BIOSERVICE-Project No.:	041502
Test Item:	Teadit 24SH
Study Director:	Dr. Achim Albrecht
Title:	Classification of Plastics - Plastic Class VI with Teadit 24SH

This study performed in the test facility BSL BIOSERVICE Scientific Laboratories GmbH was conducted in compliance with Good Laboratory Practice Regulations:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Appendix 1 to § 19a as amended on May 08, 2001, published May 14, 2001.

"OECD Principles of Good Laboratory Practice", (as revised in 1997) Paris 1998.

There were no circumstances that may have affected the quality or integrity of the study.

Study Director: Dr. Achim Albrecht

.....

Date: 13 April 2007

Statement of the Quality Assurance Unit

BSL BIOSERVICE
Scientific Laboratories GmbH
Behringstr. 6,
82152 Planegg
Germany

BSL BIOSERVICE-Project No.:	041502
Test Item:	Teadit 24SH
Study Director:	Dr. Achim Albrecht
Title:	Classification of Plastics - Plastic Class VI with Teadit 24SH

This report was audited by the Quality Assurance Unit and the conduct of this study was inspected on the following dates:

Phases of QAU Inspections	*Dates of QAU Inspections*	*Dates of Reports to the Study Director and Management*
Audit Project Protocol/ Study Plan:	July 09, 2004	July 09, 2004
Experimental Phase Audit (Project Audit):	July 20, 2004	July 20, 2004
Report Audit:	August 09, 2004	August 09, 2004

This report reflects the raw data.

Member of the
Quality Assurance Unit: ..... Helga Kötter .....

Date: ..... 13.08.2004 .....

Summary

In this study the test item was investigated according to USP Plastic Class VI – 121 °C. The tests performed were the Systemic Injection Test (intraperitoneal and intravenous administration, respectively depending on the extraction vehicle used), the Intracutaneous and the Implantation Test.

4 extracts of the test item (isotonic saline, 1 in 20 ethanol in isotonic saline, polyethylene glycol 400, and vegetable oil) were investigated in the Systemic Injection Test and the Intracutaneous Test. In the Implantation Test at least 4 strips/animal were investigated for the potential of inducing local tissue effects.

In the Systemic Injection Test no significant clinical signs were observed.

The average score in the Intracutaneous Reactivity Test was 0.

In the Implantation Test no compound-related tissue reactions were found.

Conclusions

Considering the reported data the test item Teadit 24SH meets the requirements of USP Plastic Class VI.

Introduction

Six Plastic Classes are defined. This classification is based on responses to a series of in vivo tests for which extracts, materials, and routes of administration are specified. These tests are directly related to the intended end-use of the plastic articles. The choice of extractants is representative of the vehicles in preparations with which the plastics are likely to be in contact.

In this project the test item was investigated according to USP Plastic Class VI.

With the exception of the Implantation Test, the procedures are based on the use of extracts that, depending on the heat resistance of the material, are prepared at one of three standard temperatures: 50 °C, 70 °C and 121 °C.

The Systemic Injection Tests and the Intracutaneous Test are designed to determine the systemic and local, respectively, biological responses of animals to plastics and other polymers by the single-dose injection of specific extracts.

The Implantation Test is designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the material into animal tissues.

Materials and Methods

Characterisation of the Test Item

The test item and the information concerning the test item were provided by the sponsor.

Name:	Teadit 24SH
Batch No.:	5308
Nature of material:	synthetic polymer
Sterile:	no
Storage:	at room temperature
Calculated surface:	400 cm^2 per sample
Melting temperature:	320 – 340 °C
Safety Precautions:	Routine hygenic procedures will be sufficient to assure personnel health and safety

Additional specifications, concerning the test item, provided by the sponsor can be part of the Report and will not require an amendment to Project Protocol.

Preparation of the Test Item and Administration Procedure

The test item was prepared in the following extraction vehicles:

a) Isotonic Saline, NaCl 0.9%; (Lot 3451A195, B. Braun Melsungen AG)

Dose: 50 mL/kg intravenous - Systemic Injection Test
Dose: 0.2 mL/animal - Intracutaneous Test

b) 1 in 20 solution of ethanol (Art. 159009, Lot K32152486 Merck) in Isotonic Saline, NaCl 0.9%

Dose: 50 mL/kg intravenous - Systemic Injection Test
Dose: 0.2 mL/animal - Intracutaneous Test

c) Polyethylene Glycol 400 (Lot 452670/1, Fluka); before administration diluted with 4.1 volumes of 0.9% NaCl in order to obtain a concentration of 200 mg/mL PEG for Systemic Injection Test, and with 7.4 volumes of NaCl to obtain a concentration of 120 mg/mL PEG for Intracutaneous Test

Dose: 10 g/kg intraperitoneal - Systemic Injection Test
Dose: 0.2 mL/animal - Intracutaneous Test

d) Vegetable Oil - (Cotton Seed Oil, Lot 103K0064, Sigma Chemicals)

Dose: 50 mL/kg intraperitoneal - Systemic Injection Test
Dose: 0.2 mL/animal - Intracutaneous Test

The extraction was carried out according to USP.
A ratio of 60 cm^2 of sample to 20 mL of extraction medium was used.
Extraction conditions: 121 ± 2 °C for 60 min.

e) Implant strips
at least 4 strips/animal (max ∅ 1 mm x 10 mm) - Implantation Test

The implant stripes were processed by heating in an autoclave at 121 °C for 20 minutes.

Test Animals - Systemic Injection Test

Albino mice, HsdWin: NMRI, female, 17 – 20 g at the commencement of the study

10 mice per test group (5 treated with the extract and 5 treated with the extract vehicle)

The animals were derived from a controlled full barrier maintained breeding system (SPF).

Source: Harlan Winkelmann GmbH, D-33178 Borchen.

According to Art. 9.2, No.7 of the German Act on Animal Welfare the animals were bred for experimental purposes.

Test Animals - Intracutaneous Test and Implantation Test

New Zealand White Rabbits HsdIf:NZW. Source: Harlan Winkelmann GmbH, D-33178 Borchen.

4 (Intracut. Test) rsp. 2 (Implantation) female animals/extract were used (weight > 2.5 kg).

The animals were derived from a controlled full barrier maintained breeding system (SPF).

According to Art. 9.2, No.7 of the German Act on Animal Welfare the animals were bred for experimental purposes.

Animal Husbandry

- Semi-barrier in air conditioned rooms
- Temperature: 18 ± 3 °C for rabbits and 22 ± 3 °C for mice

- Rel. humidity: 55 ± 10%
- Artificial light, sequence being 12 hours light, 12 hours dark
- Air change: at least 10 x / hour
- Free access to Altromin 2123 and Altromin 1324 maintenance diet for rabbits and mice, respectively, totally pathogene free-TPF
- Free access to tap water (drinking water, municipal residue control, microbiol. controlled periodically)
- Rabbits: Housed in ABS - plastic rabbit cages, floor 4200 cm^2
- Mice: in Macrolon Type IV-cages on Altromin saw fiber bedding, max. group size 5 animals
- Certificates of food, water and bedding are filed at BSL Bioservice
- Adequate acclimatization period

Experimental Procedure for Systemic Injection Tests

Each of five mice was injected in a test group with the extract or the extract vehicle in the control groups with a dose of 50 mL/kg (for Sodium Chloride, Alcohol in Sodium Chloride, Vegetable Oil) and 10g/kg (for Polyethylene Glycol 400).

The animals were observed immediately after injection, again 4 hours after injection, and then at least at 24, 48 and 72 hours.

Experimental Procedure for Intracutaneous Test

On the day before the test, the fur was closely clipped on the animals back on both sides of the spinal column over a sufficiently large test area.

The rabbits were injected with 0.2 mL of the extracts at five sites on one side of each animal and similarly were injected with 0.2 mL of the extract vehicle at five posterior sites on the same side of each animal.

Observations were recorded and compared to the reagent control injection sites, immediately after injection and 24 h, 48 h and 72 hours after injection.

Experimental Procedure for Implantation Test

On the day of the test, the fur of the animals was clipped on both sides of the spinal column.

At least 4 strips of the test item were implanted into the paravertebral muscle on one side of the spine of each of 2 rabbits, 2.5 to 5 cm from the midline and parallel to the spinal column, and about 2.5 cm apart from each other. In

the same manner 2 strips of USP Negative Control Plastic RS (Promochem GmbH, Lot F1) were implanted in the opposite muscle of each animal.

The animals were kept for a period of not less than 120 hours and were sacrificed at the end of the observation period by administering an overdose of an anesthetic agent. The area of the tissue surrounding the center portion of each implant strip was examined macroscopically.

Evaluation of Results

Evaluation of Results of the Systemic Injection Tests

If during the observation period none of the animals treated with the extract of the test item shows a significantly greater biological reactivity than the animals treated with the extraction vehicle, the material meets the requirements of the test.

If two or more mice die, or if abnormal behavior such as convulsions or prostration occurs in two or more mice, or if a body weight loss greater than 2 g occures in three or more mice, the test item does not meet the requirements of the test.

If any animals treated with the test item showed only slight signs of biological reactivity, and not more than one animal showed gross symptoms of biological reactivity or dies, the test will be repeated using groups of 10 test-mice.

Evaluation of Results of the Intracutaneous Test

Tissue reaction for erythema and oedema are graded according to the classification system given in table 1.

Table 1 Classification system for intracutaneous reactions

Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beef-redness) to slight eschar formation (injuries in depth)	4
Edema formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approx.1 mm)	3
Severe edema (raised more than 1mm and extending beyond the area of exposure)	4

The average erythema and oedema scores for the extract of the test item and extract vehicle are determined at every scoring interval for each rabbit. After the 72 hour scoring, all erythema scores plus oedema scores are totalled separately for each extract and extract vehicle.

Each of the totals is divided by 12 (2 animals x 3 scoring periods x 2 scoring categories) to determine the overall mean score for each extract versus each corresponding extract vehicle.

The requirements of the test are met if the difference between the test item extract and the extract vehicle mean score is 1.0 or less.

If at any observation period the average reaction to the test item extract is questionably greater than the average reaction to the extract vehicle, the test will be repeated using 3 rabbits.

Evaluation of Results of the Implantation Test

The test item and the control implant sites are observed for hemorrhage, necrosis, discolorations, and infections, and the observations are recorded. The encapsulation, if present are measured by recording the width of the capsule (from the periphery of the space occupied by the implant control and

material to periphery of the capsule) rounded to the nearest 0.1 mm. The encapsulation are scored according to Table 2.

The differences are calculated between average scores for the sample and control sites.

The requirements of the tests are met if the difference did not exceed 1.0, or if the difference between the test item and control mean scored for more than one of the four implant sites does not exceed 1 for any implanted animal.

Table 2 Evaluation of Encapsulation in the Implantation Test

Evaluation of Encapsulation in the Implantation Test

Capsule Width	*Score*
None	0
up to 0.5 mm	1
0.6 - 1.0 mm	2
1.1 - 2.0 mm	3
Greater than 2.0 mm	4

Deviation from the Project Protocol

There was no deviation from the project protocol.

Results and Discussion

In this study the test item was investigated according to USP Plastic Class VI – 121 °C. The tests performed were the Systemic Injection Test (intraperitoneal and intravenous administration, respectively depending on the extraction vehicle used), the Intracutaneous and the Implantation Test.

4 extracts of the test item (isotonic saline, 1 in 20 ethanol in isotonic saline, polyethylene glycol 400, and vegetable oil) were investigated in the Systemic Injection Test and the Intracutaneous Test. In the Implantation test at least 4 strips/animal were investigated for the potential to induce local tissue effects.

In the Systemic Injection Test no significant clinical signs and no significant changes in the weight development of the animals were obtained (Results see Annex I to this study)

The average score in the Intracutaneous Reactivity Test was 0 as compared to the injection sites of the reagent controls (Results see Annex II to this study).

In the Implantation Test no compound-related tissue reactions were found (Results see Annex III to this study).

Conclusions

Considering the reported data the test item Teadit 24SH meets the requirements of USP Plastic Class VI.

Distribution of the Report

Sponsor	1x (original)
Study Director	1x (copy)

References

Draize, J.H. (1965)
Appraisal of the Safety of Chemicals
in: Foods, Drugs and Cosmetics - Dermal Toxicity pp. 49-52
Assoc. of Food and Drug Officials of the United States, Topeka, Kansas

Draize, J.H. (1955)
Dermal Toxicity pp. 46-59
Association of Food and Drug Officials of the U.S., Washington D.C.

Annex I

Table 3: *Animal weights of the systemic toxicity test with extraction vehicles NaCl 0.9 % and NaCl 0.9 % / Ethanol*

Extraction vehicle	*Group*	*Animal number*	*Animal weight at the beginning of the study (g)*	*Animal weight at the end of the study (g)*	*Weight gain (g)*
NaCl	Test item group	1	22	24	+2
		2	21	23	+2
		3	22	25	+3
		4	22	24	+2
		5	21	23	+2
NaCl	Control group	6	23	26	+3
		7	22	25	+3
		8	20	24	+4
		9	22	25	+3
		10	20	23	+3
NaCl / Ethanol	Test item group	1	23	25	+2
		2	22	25	+3
		3	20	24	+4
		4	22	24	+2
		5	20	23	+3
NaCl / Ethanol	Control group	6	19	22	+3
		7	20	23	+3
		8	21	24	+3
		9	21	23	+2
		10	18	22	+4

Table 4: *Animal weights of the systemic toxicity test with extraction vehicles Polyethylene Glycol 400 and Cottonseed Oil*

Extraction vehicle	*Group*	*Animal number*	*Animal weight at the beginning of the study (g)*	*Animal weight at the end of the study (g)*	*Weight gain (g)*
PEG 400	Test item group	1	21	23	**+2**
		2	22	24	**+2**
		3	21	22	**+1**
		4	22	23	**+1**
		5	22	24	**+2**
PEG 400	Control group	6	20	22	**+2**
		7	21	23	**+2**
		8	19	21	**+2**
		9	21	23	**+2**
		10	20	23	**+3**
Cottonseed Oil	Test item group	1	20	22	**+2**
		2	20	22	**+2**
		3	20	22	**+2**
		4	17	19	**+2**
		5	20	22	**+2**
Cottonseed Oil	Control group	6	19	21	**+2**
		7	20	22	**+2**
		8	20	22	**+2**
		9	19	21	**+2**
		10	20	22	**+2**

Annex II

Table 5: *Results Intracutaneous Reactivity in the Rabbit - Extracts NaCl and NaCl/Ethanol*

Test Item

Animal number	Injection site	Post injectionem				24 hours after injection				48 hours after injection				72 hours after injection			
		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema	
		L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Control

Animal number	Injection site	Post injectionem				24 hours after injection				48 hours after injection				72 hours after injection			
		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema	
		L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

L = left; NaCl R = right; NaCl/Ethanol

Overall Mean Score: NaCl Test: 0 NaCl/Ethanol Test: 0
NaCl Control: 0 NaCl/Ethanol Control: 0

Control-Corrected: 0 0

Table 6: *Results Intracutaneous Reactivity in the Rabbit - Extracts PEG 400 and Cotton Seed Oil*

Test Item

Animal number	Injection site	Post injectionem				24 hours after injection				48 hours after injection				72 hours after injection			
		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema	
		L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Control

Animal number	Injection site	Post injectionem				24 hours after injection				48 hours after injection				72 hours after injection			
		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema		Erythema		Oedema	
		L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

L = left; PEG R = right; CottonSeed

Overall Mean Score: PEG Test: 0 CottonSeed Test: 0
PEG Control: 0 CottonSeed Test Control: 0

Control-Corrected: 0 0

Annex III

Table 7a: *Results Implantation - Tissue Reactions*

Test Item

Animal No.	*1*				*2*			
Implant Sites	*1*	*2*	*3*	*4*	*1*	*2*	*3*	*4*
Tissue Reaction	np	np	np	np	np	np	np	np
Haemorrhage	np	np	np	np	np	np	np	np
Necrosis	np	np	np	np	np	np	np	np
Discoloration	np	np	np	np	np	np	np	np
Infection	np	np	np	np	np	np	np	np

Control

Animal No.	*1*		*2*	
Implant Sites	*1*	*2*	*1*	*2*
Tissue Reaction	np	np	np	np
Haemorrhage	np	np	np	np
Necrosis	np	np	np	np
Discoloration	np	np	np	np
Infection	np	np	np	np

np = not present;

Table 7b: *Results Implantation-Encapsulation*

Animal No. 1	*Test Item*				*Control*	
Implant Sites	*1*	*2*	*3*	*4*	*1*	*2*
Capsule Width Score	0	0	0	0	0	0
Average		0			0	
Difference		0			0	

Animal No. 2	*Test Item*				*Control*	
Implant Sites	*1*	*2*	*3*	*4*	*1*	*2*
Capsule Width Score	0	0	0	0	0	0
Average		0			0	
Difference		0			0	